

OVERVIEW OF AMENDMENTS & REMARKS

1. SPECIFICATION: No amendments.
2. CLAIM CANCELLATION DUE TO RESTRICTION REQUIREMENT: Non-elected prior claims 11 - 34, and 36 - 50 of record under traverse have been canceled. See "SUPPLEMENTAL REQUEST FOR RECONSIDERATION OF RESTRICTION REQUIREMENT UNDER 37 CFR 1.143" mailed June 26, 1998 enclosed.
3. CLAIMS STATUS:
 - a. No canceled claims.
 - b. Amended (12) claims: 1, 6 - 10, 35, & 51 - 55.
 - c. No amendment (4) claims: 2 - 5.
 - d. New claims (3): 56 - 59.
 - e. Total (19) original patent claims pending:
(6) independent claims: 1 - 6.
 - f. (13) dependent claims: 7 - 10, 35, & 51 - 59.
4. NO REJECTION OF CLAIMS UNDER 35 USC SECTION 102 REMAIN.
5. THE REJECTION OF CLAIMS UNDER 35 USC SECTION 103(a) ARE TRAVERSED with amendments and arguments in favor of novelty, and unobviousness presented.
6. THE REJECTION OF CLAIMS UNDER 35 USC SECTION 112 ARE TRAVERSED with arguments in favor of definiteness presented.
7. A PETITION FOR (1 MONTH) EXTENSION OF TIME (Rules 136 and 17(a)-(d)) is enclosed with payment of fees (below).
8. FEE PAYMENT:
\$55.00 (check #3520) - PETITION FOR (1 MONTH) EXTENTION OF TIME (above)
\$396 (check #3519) EXCESS CLAIM FEES (below)
9. FEE STATUS: (small entity) A total of \$3181 has been paid on the present application which results in an overpayment of \$2111 per this

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AMENDMENT D which now presents (6) independent claims, and (13) dependent claims for a total of (19) claims.

BASIC NATIONAL FEE \$350

EXCESS CLAIM FEES PREVIOUSLY PAID: \$2435

EXCESS CLAIM FEES PREVIOUSLY DUE: \$324

independent claims in excess of three : $3 \times \$41 = \123

claims in excess of twenty: $6 \times \$11 = \66

multiple dependent claims: \$135

EXCESS CLAIM FEES PAID THIS AMENDMENT: \$396

independent claims in excess of three : 0

claims in excess of twenty: $36 \times \$11 = \396

OVERPAYMENT OF EXCESS CLAIM FEES \$2111

10. REQUEST FOR REFUND OF OVERPAYMENT \$2111

11. REQUEST FOR CONSTRUCTIVE ASSISTANCE

Applicant has made diligent effort to write the claims of this application in allowable condition. If for any reason the claims are not believed to be in full condition for allowance, Applicant respectfully requests the constructive assistance of Examiner in writing one or more allowable claims pursuant to MPEP 707.07(j), and in making constructive suggestions pursuant to MPEP 706.03(d) in order that this application be placed in allowable condition as soon as possible.

REMARKS

12. The multiple dependent claims were amended to include reference to more of the independent claims to provide more detailed identification of the claimed invention, and are a fortiori patentable along with the independent claims referenced. In others, the area of infection replaced the previous more technical medical terminology.

13. New multiple dependent claims 56 - 58 were added to provide more detailed identification of the source of the claimed active agent, and are a fortiori patentable along with the independent claims referenced.

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CLAIM AMENDMENTS

Amend claim 1 of record (once amended) as follows:

1. A method of treating deep tissue, or systemic fungal diseases comprising:
administration to an area of disease a suitable carrier containing a primary anti-infective [compound] agent obtainable from capsicum pepper, or an equivalent in a therapeutically effective amount.

No amendment of claims 2 - 5 of record:

2. A method of treating systemic fungal diseases selected from the group consisting of blastomycosis, coccidioidomycosis, entomophthoromycosis, or paracoccidioidomycosis comprising:
administration to an area of disease a suitable carrier containing a primary anti-infective agent obtainable from pepper, or an equivalent in a therapeutically effective amount.

3. A method of treating systemic fungal diseases selected from the group consisting of aspergillosis, candidiasis, cryptococcosis, or histoplasmosis comprising:
systemic administration to an area of disease a suitable carrier containing a primary anti-infective agent obtainable from pepper, or an equivalent in a therapeutically effective amount.

4. A method of treating fungal infections of the mucosa comprising:
administration to an area of disease a suitable carrier containing a primary anti-infective agent obtainable from a pepper plant of the genus *Capsicum*, *Peperoma*, or species *Piper retrofractum*, *Piper longum*, or *Piper nigrum* in a therapeutically effective amount.

5. A method of treating the superficial manifestations of fungal disease in the areas of the body about the face, ear, mouth, neck, and below, and deep tissue, or systemic fungal diseases comprising:
administration to the area of disease a suitable carrier containing a primary anti-infective agent obtainable from pepper, or an equivalent wherein a therapeutically effective amount is a concentration similar to oleoresin or less.

Amend claims 6 - 10, 35, and 51 - 55 of record (once amended) as follows:

6. A method of treating the superficial manifestations of fungal disease or systemic fungal diseases comprising:
administration to the area of disease a suitable carrier containing a primary anti-infective agent obtainable from pepper, or an equivalent wherein a therapeutically effective amount is a concentration within the range of ground spice or oleoresin.

202 7. A method as in any one of claims 5 or 6, wherein the disease infects the feet [is tinea pedis].

8. A method as in any one of claims 5 or 6, wherein the disease infects the body area [is tinea corporis].

9. A method as in any one of claims 5 or 6, wherein the disease infects the crotch area [is tinea cruris].

10. The method of claim 6, wherein the disease infects the scalp [is tinea capitis].

11/35. A method as in any one of claims 1 - 6, [or 4,] wherein the disease is candidiasis.

12/51. A method as in any one of claims 1 - 6, [or 4,] wherein said agent is a synthetic.

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~~52.~~ A method as in any one of claims 2, 3, 5, or 6, wherein said pepper [plant] is a Capsicum.

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~~53.~~ A method as in any one of claims 1 - [5 or] 6, wherein said agent is a capsacinoid (~~Fig. 6~~) analog.

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~~54.~~ A method as in any one of claims 2, 3, 5, or 6, wherein said plant is piperaceous.

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~~55.~~ A method as in any one of claims 2, 3, 5, or 6, wherein said agent contains a piperidine (~~Fig. 8~~) constituent.

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conclusion

[Add new claims 56 -60 as follows:]

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~~56.~~ A method as in any one of claims 1 - 6, wherein said pepper is cayenne.

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~~57.~~ A method as in any one of claims 1 - 6, wherein said pepper is paprika.

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~~58.~~ A method as in any one of claims 1 - 6, wherein said pepper is black.

RESPONSE TO REJECTION OF CLAIMS UNDER 35 USC SECTION 103(a)

Note that there are no claims presented for examination past claim 55 at this time. The original claims 1 - 90 were canceled by PRELIMINARY AMENDMENT A filed March 18, 1997.

Claims 1 - 10, 35, and 51 - 55 have been rejected under 35 U.S.C. 103(a) as being unpatentable over CHAURASIA et al. (R) and JAIN et al. (S)

This rejection is traversed.

CHAURASIA et al. and JAIN et al. are specific to individual, and combination testing of the pure essential oil of various plant species *in vitro* against various

pathogens, and non-pathogens. Essential oil is a specific component usually obtained by special (steam distillation) process with a yield of about 3% or less of the bulk mass of the plant. None of the claims specifically cite essential oil.

The claims (2 - 4) with language that could allow for inclusion of pure essential oil are directed towards medical preparations, areas of the body, and modes of administration for the actual treatment of disease caused by pathogens, none of which are suggested by the references. Neither do they mention synthetic pepper compounds (claim 51).

The references appear to presume that essential oils alone contains the active ingredient. Oleoresin (claims 5 - 10, & 52 - 55), and ground spice (claims 6, 54 & 55) contain many other ingredients not suggested by the references, and any essential oil present in them is far below the concentration found in pure essential oil as in the references.

In addition, it would appear from CHAURASIA et al. and JAIN et al. that *Piper* species (claims 2 - 10, 35, 54 & 55) are mediocre, to poor by comparison to other plant species, and other commonly used antifungals.

JAIN et al. declared the use of plant essential oils in general to show no particular advantage over standard antifungal substances commonly in use, and further stated their usefulness in dermatological products to be uncertain and controversial with topical inertness yet unconfirmed.

Among the plants JAIN et al. tested, *Zanthoxylum alatum* (not a pepper species) was the top performer, with no recommendation regarding *Piper nigrum*, which was not notable among the group.

The CHAURASIA et al. screen of three plant essential oils for antifungal activity showed *Mentha arvensis* of the mint family as preferred over *Piper nigrum*, which was inactive against fungal species *Aspergillus fumigatus* (claim 3), and *Penicillium decumbens*, a contrary suggestion.

As such, CHAURASIA et al. and JAIN et al. provide nothing that would motivated a practitioner of the art to go to the considerable trouble, and

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expense necessary to develop an antifungal medication from pepper, much less for systemic administration (claims 1 - 3, & 35), or treatment of mucosal infections (claim 4). The motivation they provide is contrary to use of pepper.

The current invention, on the other hand, asserts the superiority of pepper as a medical treatment.

The truth is, what performs well in a culture dish (*in vitro*) may do poorly in the actual treatment of disease (*in vivo*), and visa versa. But unless a candidate looks very promising preliminary results, it has little chance of being developed into a medicine and used against disease. Note also the wide variation of sensitivity to test compounds between the various organisms.

Both CHAURASIA et al. and JAIN et al. lack use, or suggestion regarding *Capsicum* pepper (claims 1, 4, & 52), which is not *piperaceous* (claim 54), and does not yield appreciable amounts of essential oil, or it's exclusive constituent capsaicinoids (claim 53). Nor do they mention piperidine constituents (claim 55).

For the reasons stated above, the cited references do not render the invention as claimed obvious to practitioners of ordinary skill in the art. As such, all rejections as to obviousness are not proper and should be withdrawn

RESPONSE TO REJECTION OF CLAIMS UNDER 35 USC SECTION 112 SECOND PARAGRAPH

Claims 53 and 55 have been rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, inthat claim 53 does not disclose what a capsaicinoid analog is, or claim 54 what a piperidine constituent is.

This rejection is traversed.

As above, claims 56 - 90 were canceled by PRELIMINARY AMENDMENT A filed March 18, 1997.

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There is no requirement that claims provide definition of terms used. See MPEP 2111.1

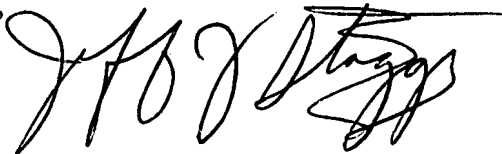
Claim terms are interpreted according to their plain meaning to practitioners of ordinary skill in the art, coupled with specification disclosure.

In addition to available prior art, the specification provides numerous examples of capsaicin, and capsaicin-like (capsaicinoids) compounds (claim 53) with basic constituent, and analog structures described (pg. 31-36), and shown in the drawing figures (6). "Synthetic" versions are also mentioned (claim 51) (pg. 31 - 33).

Likewise with the "piperidine" constituent series (claim 55).

No further amendments at this time.

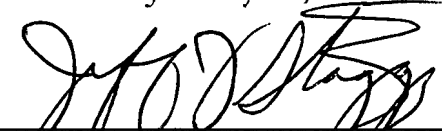
Respectfully,

 01/23/99

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Certificate of Mailing

I certify that this correspondence will be deposited with the United States Postal Service as first class mail with proper postage affixed in an envelope addressed to: "Commissioner of Patents and Trademarks, Washington, DC 20231" on January 23, 1999.

 01/23/99

Jeff J. Staggs, Applicant Date

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